

**REMARKS**

Claims 1-18 are pending in this application. Claims 10 and 15 have been amended to positively recite that the polymer has a free carboxyl group at its  $\omega$ -end. See claim 1, line 2. No new matter has been added. The Examiner is thanked for indicating claims 1-9 allowable. Favorable reconsideration is respectfully requested in view of the amendment to claims 10 and 15 and the following remarks.

***I. At page 2 of the Office Action, claims 10-18 stand rejected under 35 USC § 102(b) as being anticipated by Takeda Chemical Ind. (EPO 668073A2).***

The Examiner states that Takeda disclose a sustained-release preparation of an ester formed at a terminal carboxyl group of a straight-chain polyester which essentially consists of an  $\alpha$ -hydroxy monocarboxylic acid, wherein the polyester having a weight-average molecular weight of about 1,500 to about 50,000 which anticipates the claimed invention. The Examiner points to page 20 and the claims of Takeda.

Anticipation under 35 USC § 102(b), requires that a single prior art reference teach each and every element of the claimed invention. In view of the following, this rejection is respectfully believed to be overcome. A brief discussion of Takeda is set forth below.

Takeda discloses a polymer of hydroxycarboxylic acid which polymer is an ester. Specifically, the  $\omega$ -terminal carboxyl group is esterified. Takeda discloses, on page 3, lines 18-25, that the polymer produced by the disclosed ring opening polymerization process has no free terminal carboxyl group.

Claims 10 and 15 of the invention, are directed to a biodegradable polymer obtained by the production process as set forth in claims 1 and 7. Claims 10 and 15 have been amended to positively recite that the polymer has a free carboxyl group at the  $\omega$ -end. Claims 1 and 7 recite a process for producing a biodegradable polymer having a free carboxyl group at the  $\omega$ -end.

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The inventive process is a ring-opening polymerization process. Please see the specification at page 2, lines 4-8. Conventional ring-opening polymerization processes result in a protected carboxyl group. This protected carboxyl group makes it difficult to use the polymer for sustained-release application. The present polymer has a  $\omega$ -end free carboxyl group, which is produced by removing the protective group, and which has a superior controlled-release action.

In view of the above, it is submitted that Takeda do not teach each and every element of the claimed invention as required for anticipation under 35 USC § 102(b), since Takeda do not teach a polymer having a free carboxyl group at its  $\omega$ -end. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

In view of the foregoing amendment and remarks, it is respectfully submitted that the application is in condition for allowance. Early notice to that effect is solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

If the Examiner has any questions regarding this amendment and response, the application in general, or has any suggestions for placing the application in condition for allowance, the Examiner is requested to call the undersigned at the number listed below.

Respectfully submitted,

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**Version with Markings to**  
**Show Changes Made**

**APPENDIX A**

Please amend claims 10 and 15 as indicated below.

10. (Twice Amended) A biodegradable polymer comprising a free carboxyl group at the  $\omega$ -end,  
[obtained by the production] produced by the process as set forth in claim 1.

15. (Amended) A biodegradable polymer comprising a free carboxyl group at the  $\omega$ -end,  
[obtained by the production] produced by the process as set forth in claim 7.